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EXAMINER	
LOUIS, LATOYA M	

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4177	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/596,034	BASSIN, DAVID	
	Examiner	Art Unit	
	LATOYA LOUIS	4177	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *112-134* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *112-134* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 May 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/25/2006, 7/31/2007, 5/19/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is responsive to papers filed 5/25/2006. Claims 112-134 are pending. The claim to benefit under 35 USC 119(e) is acknowledged.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 112-114 and 121 are rejected under 35 U.S.C. 102(b) as being anticipated by Cotner et al. US Pat. No. 5, 645, 054.

Regarding claim 112, Cotner et al. discloses in fig. 1 an apparatus for providing ventilatory assistance to a patient comprising:

- a control mechanism (10) for deriving two error signals (the timing circuit 27 as first error signal indicates when there has been no normal inhalation for 8 seconds. See in combination col. 6 lines 65-67-col. 7 lines 1-14 where the term "logical one" represents normal inhalation, col. 9 lines 25-35. The critical flow limitations as second error signal are false inhalation indications sensed by flow sensor 28 and eliminated by antifalsing circuit 17 as described in col. 6 lines 56-64, col. 8 lines 11-26, and col. 8 lines 42-60)
- each of which is a function of the same target value (the first error signal is a function of normal inhalation as target value because it determines when there has been no normal inhalation for 8 seconds and then causes a ventilator response col. 9 lines 25-35. The second error signal

indicates false inhalation, or lack of normal inhalation as target value, and thus is also related to normal inhalation and ventilator response col. 8 lines 42-60)

- and a respective one of two patient ventilation measures (the error signals are derived from, dependent on, and thus are a function of the output of flow sensor 28 and output of dynamic reference circuit 25 as two ventilation measures as described in col. 6 lines 44-67),
- the two patient ventilation measures having respective relatively fast and relatively slow speeds of response (the output of the flow sensor 28 has a relatively fast response compared with output "R" of dynamic reference circuit 25. Likewise output "R" of dynamic reference circuit 25 has a relatively slow response in comparison with the output of flow signal 25 as disclosed in col. 6 lines 13-30)
- said control mechanism (10) further deriving two control responses (from unit 38) to respective ones of said two error signals (the control response of unit 38 to the first error signal is to increase the blower speed up to 20cm of water or until normal inhalation is reached as disclosed in col. 9 lines 41-48 and col. 9 lines 7-25. The control response of unit 38 to the second error signal, represented by letter "C" in fig. 3, is to keep the blower speed at 2.5cm of water until the first error signal is detected at letter "D" as further disclosed in col. 9 lines 64-67- col. 10 lines 1-2, col. 9 lines 12-18.)
- and combining said two control responses to produce an overall control response (the overall response of the blower unit 38) that increasingly favors the control response (increasing blower speed) to the error signal (output of timing circuit 27) that is a function of the ventilation measure with the faster speed of response (output of flow sensor 28) over the control response (maintaining base speed 2.5) to the error signal (critical flow) that is a function of the ventilation

measure with the slower speed of response ("R") as the ventilation measure with the faster speed of response (output of flow sensor 28) becomes increasingly less than said target value (Referring to figs. 2A-2C, as the output of the flow sensor curve represented by letter "M" in fig. 2A increasingly fails to meet normal inhalation as target value as time increases by not decreasing below "R" through the end of period "Y" representing 8 seconds, the blower unit's overall response is to increase blower speed thereby favoring the same control response of the first error signal represented by the output of timing circuit 27. See also col. 8 lines 11-25, col. 9 lines 7-24, and fig. 3 with col. 9 lines 64-67-col. 10 lines 1-3);

- and a ventilator (blow unit 12) responsive to said overall control response for controlling the pressure of air delivered to said patient (col. 9 lines 42-48, col. 5 lines 40-49).

Regarding claim 113, Cotner et al. discloses that each of said two control responses is a function of the amplitude and sign of the respective one of said error signals (Both of the control responses are dependent on whether the timing circuit has an increasing amplitude up to a positive value of 8 sec. or not, or alternatively, whether the timing circuit has a positive increasing sign up to a high amplitude of 8 seconds or not as taught in col. 9 lines 33-35, col. 8 lines 65-67-col. 9 lines1-3) so that the control response to the error signal that is a function of the ventilation measure with the faster speed of response (increasing blower speed) is more vigorous than the control response to the error signal that is a function of the ventilation measure with the slower speed of response (maintaining base blower speed). (It is disclosed that the blower can increase speed from 2.5 to the max speed of 20cm water in as little as 2 seconds col. 9 lines 41-44. It is also disclosed that the blower speed is maintained during normal inhalation and for 8 seconds after critical flow is detected as disclosed in fig. 3C and col. 9 lines 64-67-col.

10 lines 1-2, col. 9 lines 12-13. Therefore, the control response of increasing blower speed is more vigorous).

Regarding claims 114 and 121 Cotner et al. discloses in fig. 3 that the degree of control exercised by said ventilator (blow unit 12:fig. 1) increases with the magnitudes of said two error signals (when the second error signal indicates the onset of critical flow at "C" and the first error signal increases to 8 seconds represented at "D", the response of the blower unit as ventilator is to increase ventilation pressure up to a max represented by "I").

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 115, 122, 125, and 128-134 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cotner et al. in view of Berthon-Jones US Pat. No. 6, 951, 217 B2 hereinafter Berthon-Jones '217.

Regarding claim 129, Cotner et al. does not specifically disclose that the ventilator includes a servo control mechanism whose gain is adjusted in accordance with the magnitudes of said error signals. However, Berthon-Jones '217 discloses that the ventilator (fig. 2) includes a servo control mechanism (19) whose gain is adjusted in accordance with the magnitudes of said error signals (the ventilator pressure amplitude A as gain or alternatively the servo controller's gain G is adjusted in proportion to the error signals e as shown in the formula in col. 9 line 18 and in col. 9 lines 6-28. See also the formula deriving mask pressure in col. 9 lines 38-47 which shows relationship with A which is related to e and G. See also col. 8 lines 53-67, col. 7 lines 57-63). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the invention of Cotner et al. with the features of the servo controller gain adjustment as taught by Berthon-Jones '217 to provide a closed loop feedback mechanism to more quickly correct ventilation errors. It is noted that both devices are directed to controlled ventilators for treating hypopneas in respiratory impaired patients.

Regarding claim 130, Cotner et al. does not specifically disclose that the gain increases with the magnitudes of said error signals. However, Berthon-Jones '217 discloses that the gain increases with the magnitudes of said error signals. (The ventilator pressure amplitude A as gain or alternatively the servo controller's gain G is increased in proportion to an increase in error signals e as shown in the formula on col. 9 line 18 and in col. 9 lines 6-28. See also the formula deriving mask pressure in col. 9 lines 38-47 which shows relationship with A which is related to e. and G. See also col. 8 lines 40-67, col. 7 lines 57-63). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the invention of Cotner et al. with the features of the servo controller gain increase as taught by Berthon-Jones

'217 to provide a more efficient means of correcting errors in ventilation pressures. It is noted that both devices are directed to controlled ventilators for treating hypopneas in respiratory impaired patients.

Regarding claims 115, 122, and 131 Cotner et al. does not completely discloses that for equal error signals below and above said target value, the degree of control exercised by said ventilator is greater for error signals below said target value. However, Berthon-Jones '217 discloses an apparatus (fig. 2) for providing ventilatory assistance to a patient wherein for equal error signals (col. 9 lines 9-25) below and above said target value (col. 8 lines 35-39), the degree of control exercised by said ventilator is greater for error signals below said target value (Since error signals are only 95% of actual flow, error signals will be generated when ventilatory support is added to the patients attempts at breathing as discussed in col. 10 lines 63-67-col. 11 lines 1-7. Therefore, as discussed, the ventilator support will remain at 3 cm water and there will be no change of ventilatory support. However, if the error signal drops below the target ventilation, the ventilator quickly increases pressure to a maximum of 10 cm water to bring airflow back up to 95% of the previous actual ventilation as discussed in col. 11 lines 7-13, and fig. 6 with col. 11 lines 30-47. See also fig. 5 showing difference between target and average ventilation). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the invention of Cotner et al. with the features of the comparison between error signals and target value of Berthon-Jones '217 to provide greater ventilatory support during periods of low patient initiated ventilation. It is noted that both devices are directed to ventilators with error signals for treating hypopneas in respiratory impaired patients.

Regarding claim 132, Cotner et al. does not specifically disclose that gain is varied more aggressively for conditions of hypoventilation than for conditions of hyperventilation. However, Berthon Jones '217 discloses that gain is varied more aggressively for conditions of hypoventilation than for conditions of hyperventilation (When ventilatory support is added to the patient's attempts at breathing, the patient's actual flow exceeds the target which is only 95% of actual flow and thus the patient is hyperventilated col. 10 lines 63-67-col. 11 lines 1-7. As shown, the ventilator support will remain at 3cm water for this type of hyperventilation and there will be no change of ventilatory support. However, if the error signal drops below the target ventilation, the ventilator quickly increases pressure to a maximum of 10cm water to bring airflow back up to 95% of the previous actual ventilation as discussed in col. 11 lines 7-13, and fig. 6 with col. 11 lines 30-47. See also fig. 5 showing difference between target and average ventilation). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the invention of Cotner et al. with the features of the gain variation of Berthon-Jones '217 to provide greater ventilatory support during periods of low patient initiated ventilation. It is noted that both devices are directed to ventilators with error signals for treating hypopneas in respiratory impaired patients.

Regarding claim 125, Cotner does not specifically disclose that the control mechanism determines the phase of the current breathing cycle and adjusts said overall control response to be a function of the amplitude at the determined phase of the current breathing cycle of an amplitude-versus-phase template that is appropriate for a normal breathing cycle. However, Berthon-Jones '217 discloses in fig. 2 that the control mechanism (16) determines the phase of the current breathing cycle (col. 9 lines 38-40) and adjusts said overall control response (the

amount of pressure delivered "Pmask" as control response seen in the formula on col. 9 line 43) to be a function of the amplitude at the determined phase of the current breathing cycle (See again the formula on col. 9 line 43 which shows Pmask to be a function of amplitude A multiplied by the current phase) of an amplitude-versus-phase template that is appropriate for a normal breathing cycle (see fig. 3. and col. 9 lines 40-41, 48-57. See also the relationship of relationship of A in col. 9 line 18). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the invention of Cotner et al. with the features of determining the phase to control the ventilator response of Berthon-Jones '217 to provide a more comfortable and safe ventilation response that cycles with the patient's respiratory cycle. It is noted that both devices are directed to controlled ventilators for treating hypopneas in respiratory impaired patients.

Regarding claim 128, Cotner et al. does disclose that each of said error signals is a clipped integral of the respective patient ventilation measure minus said target value. However, Berthon-Jones '217 discloses that each of said error signals is a clipped integral of the respective patient ventilation measure minus said target value (the error signal is defined as the ventilation measure minus the target value. Therefore as shown in the formula of the disclosure in col. 9 lines 6-22 the error signal is being taken as a clipped integral). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the invention of Cotner et al. with the features of the clipped integral as taught by Berthon-Jones '217 to provide a convenient range to operate the ventilator pressure. It is noted that both devices are directed to controlled ventilators for treating hypopneas in respiratory impaired patients.

Regarding claim 133, Cotner et al. does not specifically disclose that the ventilator is flow-triggered and phase cycled. However, Berthon-Jones '217 discloses that the ventilator is flow-triggered and phase cycled (col. 9 lines 48-55). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the invention of Cotner et al. with the features of ventilator being also phase cycled as taught by Berthon-Jones '217 to provide a more reliable way to insure proper ventilation in the event of patient apnea or hypopnea.. It is noted that both devices are directed to controlled ventilators for treating hypopneas in respiratory impaired patients.

Regarding claim 134, Cotner et al. does not specifically disclose that the ventilator withdraws ventilation support more gradually when the patient is over-ventilated than when the patient is under-ventilated. However, Berthon-Jones discloses that the ventilator withdraws ventilation support more gradually when the patient is over-ventilated than when the patient is under-ventilated (As seen from fig. 6, when the patient has a cessation of spontaneous effort representing hypoventilation, the ventilator pressure increases rapidly to a maximum within 4 breaths. See also col. 11 lines 28-37. However, when the patient resumes normal effort, the respiratory airflow seen as the second graph is at first much higher than normal representing hyperventilation. The ventilator pressure reduces back down to base pressure much slower over 5 breaths. Therefore, the ventilator responded more quickly during hypoventilation). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the invention of Cotner et al. with the features of ventilator withdrawing hyperventilation more slowly as taught by Berthon-Jones '217 to provide a smoother more comfortable way of withdrawing support without waking a sleeping patient. It is noted that both

devices are directed to controlled ventilators for treating hypopneas in respiratory impaired patients.

6. Claim 124 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cotner et al. in view of the article entitled "An Adaptive Lung Ventilation Controller" (of record) by Laubscher et al.

Regarding claim 124, Cotner doesn't teach that the target value is an alveolar ventilation that takes into account the patient's anatomical or physiologic dead space. However, Laubscher at al. discloses an apparatus (fig. 2) for providing ventilatory assistance wherein said target value "V'ga" is an alveolar ventilation (page 51, col. 2, 4th paragraph) that takes into account the patient's anatomical or physiologic dead space "VD" (the target value "V'ga" is a desired ventilation entered by a user as in page 52 col. 1 paragraph 2 that takes into account the patient's physiologic dead space VD as seen in page 52 col. 1 paragraph 2 and in formula (2) on page 51). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the invention of Cotner et al. with the features of taking physiologic dead space into account for target ventilation of Laubscher et al. to provide more accurate ventilation in people with lung disease. It is noted that both devices are directed to controlled ventilators using target ventilation to treat lung conditions.

7. Claims 116, 117, and 123 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cotner et al. in view of Berthon-Jones '217 and further in view of the article entitled "An Adaptive Lung Ventilation Controller" by Laubscher et al.

Regarding claims 116 and 123, Cotner et al. doesn't teach that the target value is an alveolar ventilation that takes into account the patient's anatomical or physiologic dead space.

However, Laubscher at al. discloses an apparatus (fig. 2) for providing ventilatory assistance wherein said target value "V'ga" is an alveolar ventilation (page 51, col. 2, 4th paragraph) that takes into account the patient's anatomical or physiologic dead space "VD" (the target value "V'ga" is a desired ventilation entered by a user as in page 52 col. 1 paragraph 2 that takes into account the patient's physiologic dead space VD as seen in page 52 col. 1 paragraph 2 and in formula (2) on page 51). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the invention of Cotner et al. with the features of taking physiologic dead space into account for target ventilation of Laubscher et al. to provide more accurate ventilation in people with lung disease. It is noted that both devices are directed to controlled ventilators using target ventilation to treat lung conditions.

Regarding claim 117, Cotner does not specifically disclose that the control mechanism determines the phase of the current breathing cycle and adjusts said overall control response to be a function of the amplitude at the determined phase of the current breathing cycle of an amplitude-versus-phase template that is appropriate for a normal breathing cycle. However, Berthon-Jones '217 discloses in fig. 2 that the control mechanism (16) determines the phase of the current breathing cycle (col. 9 lines 38-40) and adjusts said overall control response (the amount of pressure delivered "Pmask" as control response seen in the formula on col. 9 line 43) to be a function of the amplitude at the determined phase of the current breathing cycle (See again the formula on col. 9 line 43 which shows Pmask to be a function of amplitude A multiplied by the current phase) of an amplitude-versus-phase template that is appropriate for a normal breathing cycle (see fig. 3. and col. 9 lines 40-41, 48-57. See also the relationship of relationship of A in col. 9 line 18). Therefore, it would have been obvious to one of ordinary

skill in the art at the time the invention was made to combine the invention of Cotner et al. with the features of the determining the phase to control the ventilator response Berthon-Jones '217 to provide a more comfortable and safe ventilation response that cycles with the patient's respiratory cycle. It is noted that both devices are directed to controlled ventilators for treating hypopneas in respiratory impaired patients.

8. Claims 126 and 127 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cotner et al. in view of Berthon-Jones '217 and in view of Berthon-Jones US Pat. No. 6, 532, 957 B2, hereinafter Berthon-Jones '957.

Regarding claim 126, Cotner et al. does not specifically disclose that said control mechanism determines the phase of the current breathing cycle by relating respiratory airflow and its rate of change to different phases of a normal breathing cycle. However, Berthon-Jones '957 discloses an apparatus (fig. 1b) for providing ventilatory assistance wherein said control mechanism (16) determines the phase of the current breathing cycle by relating respiratory airflow and its rate of change to different phases of a normal breathing cycle (Most clearly seen in fig. 28, airflow and it's rate of change are compared to different phases of the breathing cycle through fuzzy logic sets to determine the instantaneous phase. See also col. 9 lines 39-41, col. 10 lines 59—67-col. 10 lines 1-8, specifically steps 12-16. See also Table 1 and Table 2). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the invention of Cotner et al. with the features of determining phase from airflow and airflow derivative as taught by Berthon-Jones '957 to provide a more accurate means to detect the patient's respiratory phase. It is noted that both devices are directed to controlled ventilators for treating hypopneas in respiratory impaired patients.

Regarding claim 127, Cotner et al. does not disclose that the control mechanism determines the phase of the current breathing cycle by applying a set of fuzzy logic rules. However, Berthon-Jones '957, discloses that the control mechanism determines the phase of the current breathing cycle by applying a set of fuzzy logic rules. (Most clearly seen in fig. 28, airflow and its rate of change are compared to fuzzy logic rules to determine the instantaneous phase. See also col. 9 lines 39-41, col. 10 lines 59—67-col. 10 lines 1-8, specifically steps 12-16. See also Table 1 and Table 2). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the invention of Cotner et al. with the features of determining phase from fuzzy logic rules as taught by Berthon-Jones '957 to provide a more realistic and comfortable respiratory cycle. It is noted that both devices are directed to controlled ventilators for treating hypopneas in respiratory impaired patients.

9. Claims 118-120 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cotner et al. in view of Berthon-Jones '217 and in view of Laubscher et al, and further in view of Berthon-Jones '957.

Regarding claim 118, Cotner et al. does not specifically disclose that said control mechanism determines the phase of the current breathing cycle by relating respiratory airflow and its rate of change to different phases of a normal breathing cycle. However, Berthon-Jones '957 discloses an apparatus (fig. 1b) for providing ventilatory assistance wherein said control mechanism (16) determines the phase of the current breathing cycle by relating respiratory airflow and its rate of change to different phases of a normal breathing cycle (Most clearly seen in fig. 28, airflow and it's rate of change are compared to different phases of the breathing cycle through fuzzy logic sets to determine the instantaneous phase. See also col. 9 lines 39-41, col.

10 lines 59—67-col. 10 lines 1-8, specifically steps 12-16. See also Table 1 and Table 2). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the invention of Cotner et al. with the features of determining phase from airflow and airflow derivative as taught by Berthon-Jones '957 to provide a more accurate means to detect the patient's respiratory phase. It is noted that both devices are directed to controlled ventilators for treating hypopneas in respiratory impaired patients.

Regarding claim 119, Cotner et al. does not disclose that the control mechanism determines the phase of the current breathing cycle by applying a set of fuzzy logic rules. However, Berthon-Jones '957, discloses that the control mechanism determines the phase of the current breathing cycle by applying a set of fuzzy logic rules. (Most clearly seen in fig. 28, airflow and its rate of change are compared to fuzzy logic rules to determine the instantaneous phase. See also col. 9 lines 39-41, col. 10 lines 59—67-col. 10 lines 1-8, specifically steps 12-16. See also Table 1 and Table 2). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the invention of Cotner et al. with the features of determining phase from fuzzy logic rules as taught by Berthon-Jones '957 to provide a more realistic and comfortable respiratory cycle. It is noted that both devices are directed to controlled ventilators for treating hypopneas in respiratory impaired patients.

Regarding claim 120, Cotner et al. does disclose that said overall control response is a clipped integral of a function of both of said error signals. However, Berthon-Jones '217 discloses that said overall control response (response of amplitude and/or gain of ventilator) is a clipped integral of a function of both of said error signals (col. 9 lines 6-22). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to

combine the invention of Cotner et al. with the features of the clipped integral as taught by Berthon-Jones '217 to provide a convenient range to operate the ventilator pressure. It is noted that both devices are directed to controlled ventilators for treating hypopneas in respiratory impaired patients.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Isaza et al. US Pat. No. 5, 319, 540 discloses system and method of controlling a ventilator with multiple error signals, target ventilation and control means.

Du US Pat. No. 6, 622, 726 B1 discloses gradually tapering ventilator for hyperventilation that is phase cycled and flow triggered.

O'Mahoney US Pat. No. 6, 321, 748 B1 discloses closed loop control ventilator with error signals that control ventilatory response. The ventilator is also flow triggered.

Poezevera et al. US Pat. No, 6, 773, 404 B2 discloses a ventilator system with two separate ventilation measures.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LATOYA LOUIS whose telephone number is (571)270-5337. The examiner can normally be reached on Monday-Friday, 9:30am-7pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jackson can be reached on 571-272-4697. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/L. L./
Examiner, Art Unit 4177
11/23/2009

/Gary Jackson/
Supervisory Patent Examiner
Art Unit 4177